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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/526,323 | 10/03/2005 | Richard H Ebright | 744-47 PCT/US | 6511 |

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| EXAMINER |
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KHANNA, HEMANT

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/526,323

Applicant(s)

EBRIGHT, RICHARD H

Examiner

Hemant Khanna

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 78-120 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Upon further consideration and in light of the Applicant's amendments dated June 15, 2006, the previous restriction has been vacated and a new election/restriction is instituted.

In response, the Applicant's election has been addressed to the extent that they read on the newly instituted restriction.

In the Remarks/Arguments dated June 15, 2006, the Applicant amended claims 85, 86, 88-90, 92, 94-96, and added claims 98-120. Further, the Applicant elected the species of [Cy3-Lys₁₃]MccJ25 in response to the Examiner's request for a species election dated May 17, 2006, to which the claims would be restricted if no generic claim is finally held allowable.

The Examiner acknowledges the Applicant's remarks and comments with respect to the new claims. The Examiner respectfully submits that in view of the new claims the shared technical feature described in base claim 78 was reconsidered, and a lack of single general inventive concept under PCT Rule 13.1 is now determined by the Examiner as set forth below.

As a consequence, the Examiner respectfully requests for a new restriction requirement and election of species on the amended claims.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 78-83 drawn to a peptide that differs in amino acid sequence from MccJ25 by an amino acid substitution, insertion, or deletion and that binds to bacterial RNAP

Group II, claim(s) 84-103, drawn to a method for identifying an agent that binds to bacterial RNAP comprising detecting at least one of the presence, extent, concentration-dependence, or kinetics of binding and inhibition of the agent to homologous RNAP.

Group III, claim(s) 104-120, drawn to a method for identifying an agent that binds to bacterial RNAP in competition with a reference compound and detects at least one of the presence, extent, concentration-dependence, or kinetics of binding and inhibition of the reference compound to homologous RNAP.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The MPEP states if an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. Here the independent claim 78, is not free of the prior art. The shared technical feature (a peptide that differs in sequence from microcin J25 by an amino acid substitution, insertion, or deletion and that binds to RNAP) is anticipated by Glinskii G. (WO 99/43338), and therefore is not a special technical feature within the meaning of PCT Rule 13.2.

With respect to the Group of inventions, Groups I-III, because the technical relationship among the claimed inventions involving a peptide variant of microcin J25 that binds to RNAP does not constitute a "special technical feature", more than one invention comprising the peptide agent of Group I, the methods of Group II that identify the agent, or the methods of Group III that utilize a reference compound to identify the agent cannot be permitted in one application.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The analogs in claims 78-83, RNAP (bacterial, eukaryotic, mutant) or a fragment thereof in claims 85, 88, 90, 99, 101, 106, 117, 118, organisms selected from *Escherichia coli* or *Bacillus subtilis* in claims 86, 89, 99, 106, 117, the activities in claims 96, 100.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the shared technical feature is anticipated by Glinskii G. (WO 99/43338). The analogs in Group I are drawn to different sequences of Microcin J25 modified with a detectable group, each with a unique structure and sequence. The RNAP, fragments and mutants thereof in Groups II

and III, are drawn to varying sequences, and each member cannot be substituted for the other, with the expectation that the same intended result would be achieved. The organisms of *Escherichia coli* and *Bacillus subtilis* in Group II-III are model organism drawn to Gram-negative and Gram-positive bacteria. The activities in Group II utilize varying reagents and steps to determine effectiveness of an agent.

Applicant is required, in reply to this action, to elect a single group of inventions and a single species within that group. Should Group I be elected, then the applicant is required to elect a single species of a MccJ25 analog that is modified with a detectable group. Should Group II-III be elected, a single species of RNAP, organism and activity must be completely specified, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Hemant Khanna
October 2, 2006



Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600